Announcement of the National Medical Products Administration on Issuing the Measures for the Administration of Medicinal Product Recalls[1]

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In order to implement the requirements of the *Drug Administration Law of the People's Republic of China*, the *Vaccine Administration Law of the People's Republic of China*, and other relevant laws and regulations, the National Medical Products Administration (NMPA) has organized the revision of the Drug Recall Management Measures, which are hereby promulgated and shall come into force as of November 1, 2022.

Attachment: Drug Recall Management Measures

National Medical Products Administration

October 24, 2022

Chapter I: General Provisions

Article 1 These Measures are formulated in accordance with the *Drug Administration Law of the People's Republic of China*, the *Vaccine Administration Law of the People's Republic of China*, the *Regulations for the Implementation of the Drug Administration Law*, and other laws and regulations, to strengthen drug quality supervision and ensure public drug safety.

Article 2 These Measures shall apply to the recall and its supervision of drugs manufactured and marketed within the territory of the People's Republic of China.

Article 3 For the purposes of these Measures, a *"drug recall"* refers to the activity whereby the marketing authorization holder (hereinafter referred to as the "MAH") retrieves drugs that have already been marketed and are found to have quality issues or other safety risks, in accordance with prescribed procedures, and takes corresponding measures to promptly control risks and eliminate hazards.

1 Translated by Health Law Asia – Pharmaceutical, Medical Device, and Cosmetics Law

Article 4 For the purposes of these Measures, "*quality issues or other safety risks*" refer to conditions caused by drug research, manufacturing, storage, transportation, labeling, etc., that render the drug non-compliant with legal requirements or otherwise pose unreasonable risks that may endanger human health and life.

Article 5 The MAH is the principal entity responsible for controlling risks and eliminating hazards. It shall establish and improve a drug recall system, collect information related to drug quality and safety, investigate and evaluate potential quality issues or safety risks, and promptly recall any drugs found to have such issues.

Drug manufacturers, drug distributors, and drug-using entities shall actively assist the MAH in investigating and evaluating potential quality issues or safety risks, and shall cooperate with the MAH to fulfill recall obligations by timely communicating and reporting drug recall information and controlling and retrieving the affected drugs.

Article 6 If drug manufacturers, distributors, or using entities discover that the drugs they produce, sell, or use may have quality issues or other safety risks, they shall promptly notify the MAH. Where necessary, they shall suspend production, release, sale, and use of the drugs, and report to the local drug regulatory authority of the province, autonomous region, or municipality directly under the Central Government. The information reported and notified must be truthful.

Article 7 MAHs, drug manufacturers, distributors, and using entities shall establish and implement drug traceability systems in accordance with regulations, maintain complete records of purchase and sales, and ensure traceability of marketed drugs.

Article 8 Drug regulatory authorities of provinces, autonomous regions, and municipalities directly under the Central Government shall be responsible for supervising and managing drug recalls within their respective jurisdictions.

Drug regulatory authorities at the municipal and county levels shall assist in coordinating relevant drug recall work and supervising the cooperation of drug distributors and using entities within their administrative regions.

The National Medical Products Administration shall guide the management of drug recalls nationwide.

Article 9 The NMPA and drug regulatory authorities of provinces, autonomous regions, and municipalities directly under the Central Government shall, in accordance with relevant information disclosure systems, publicly disclose drug quality or safety risk information and recall information through effective means. When necessary, relevant information shall also be shared with the corresponding health authorities.

The MAH shall formulate an information disclosure system for drug recalls and proactively disclose drug recall information in accordance with the law.

Chapter II: Investigation and Evaluation

Article 10 The MAH shall proactively collect and record information on drug quality problems, adverse drug reactions/events, and other safety risks, and investigate and assess any potential quality issues or safety hazards.

Drug manufacturers, distributors, and using entities shall cooperate with the MAH in such investigations and provide relevant materials.

Article 11 The investigation of potential quality issues or safety risks in drugs shall be based on actual circumstances and may include:

1-Types, scope, and causes of adverse drug reactions/events;

2-Whether the drug formulation and manufacturing process comply with approved standards and procedures;

3-Whether the manufacturing process complies with Good Manufacturing Practices (GMP) and any changes comply with regulatory requirements;

4.Whether storage and transportation meet Good Distribution Practices (GDP);

5-Whether usage aligns with clinical guidelines, indications, and labeling;

6-Composition and proportion of the primary user group;

7-Affected batches, quantities, and distribution scope;

8-Other factors that may affect drug quality and safety.

Article 12

Key aspects of evaluating drugs with quality issues or safety risks include:

1-Likelihood of causing harm and whether harm has occurred;

2-Impact on main user populations;

3-Effects on special groups such as elderly, children, pregnant women, patients with liver/kidney impairment, surgical patients, etc.;

4-Severity and urgency of harm;

6-Consequences caused by the harm.

Article 13 Drug recalls are classified by severity as follows:

1.Class I Recall: The use of the drug may or has caused serious health harm;

2.Class II Recall: The use may or has caused temporary or reversible health harm;

3.Class III Recall: Use generally will not cause harm, but recall is required for other reasons.

Article 14

Based on the results of investigation and evaluation and the recall classification, the MAH shall prepare an evaluation report and scientifically formulate a recall plan.

The evaluation report shall include:

1-Specific details of the recalled drug (name, specification, batch, etc.);

2-Reason for recall;

3-Results of investigation and evaluation;

4-Recall classification.

The recall plan shall include:

1-Production and sales status and the number of drugs to be recalled;

2-Specific measures of recall (organization, scope, timeline);

3-Channels and scope for information disclosure;

4-Expected recall outcome;

5-Measures for handling recalled drugs;

6-Contact person’s name and contact details.

Chapter III: Voluntary Recall

Article 15 After investigation and assessment, where the marketing authorization holder (MAH) determines that a drug presents a quality issue or other safety hazard, the holder shall promptly decide to initiate and implement a recall. Simultaneously, the recall information shall be disclosed to the public via the enterprise’s official website or through media outlets relevant to the pharmaceutical industry. The recall information shall include the following details: Drug name, Specifications, Batch number, Marketing authorization holder, Manufacturing enterprise, Reason for the recall, Recall classification (level), and other relevant information.

For Class I and Class II recalls, the MAH shall also apply for the recall information to be published on the website of the provincial, autonomous regional, or municipal people's government drug regulatory authority in the place where the MAH is located. The recall information published on these regional websites shall be linked to the website of the National Medical Products Administration (NMPA).

Article 16 Upon deciding to initiate a drug recall, the MAH shall issue a recall notice within the following timeframes: For a Class I recall, within 1 day, For a Class II recall, within 3 days, For a Class III recall, within 7 days.

The recall notice shall be sent to the drug manufacturing enterprises, drug distribution enterprises, and drug-using institutions. At the same time, the MAH shall file with the provincial, autonomous regional, or municipal drug regulatory authority the investigation and assessment report, the recall plan, and the recall notice.

The recall notice shall include the following elements:

1-Specific details of the recalled drug, including name, specifications, batch number, etc.;

2-Reason for the recall;

3-Recall classification (level);

4-Recall requirements, such as immediate suspension of production, release, sale, and use; forwarding of the recall notice, etc.;

5-Recall handling measures, such as labeling of outer packaging for recalled drugs, segregation and storage procedures, storage and transportation conditions, and supervised destruction, among others.

Article 17 During the implementation of a recall, the marketing authorization holder (MAH) shall report the progress of the recall to the drug regulatory authority of the province, autonomous region, or municipality where it is located: For a Class I recall, daily; For a Class II recall, every 3 days; For a Class III recall, every 7 days.

Throughout the recall process, the MAH shall promptly assess the effectiveness of the recall. If it is found to be incomplete, the recall plan shall be revised, and the scope of the recall expanded or restarted. If the recall plan is changed, the revised plan must be filed in a timely manner with the local drug regulatory authority at the provincial, autonomous region, or municipal level.

Article 18 The MAH shall specify the labeling and storage requirements for recalled drugs. The external packaging, segregation, and storage of recalled drugs shall be clearly distinguishable from normal drugs to prevent errors and confusion. For drugs requiring special storage conditions, the required conditions must be maintained throughout storage and transportation.

Article 19 If recalled drugs need to be destroyed, the destruction shall be carried out under the supervision of one of the following: the MAH, the drug manufacturer, the local drug regulatory authority at the county level or above, or a notary organization located where the recalled drugs are stored.

If risks can be eliminated by relabeling, revising and updating the instructions, or repackaging, or if decoction pieces of traditional Chinese medicine do not meet drug standards but remain safe and effective, and the issues can be resolved through reworking, such drugs may be appropriately treated and re-marketed. All such actions must comply with relevant Good Manufacturing Practice (GMP) requirements and must not extend the drug's shelf life or expiry date.

The MAH must maintain detailed records of the handling of recalled drugs. These records must be retained for 5 years and for at least 1 year beyond the drug's expiration date, whichever is longer.

Article 20 In accordance with Article 82 of the *Drug Administration Law*, the MAH shall, within 10 working days of completing the recall, report the details of the recall and its handling to the local drug regulatory authority and health authorities at the provincial, autonomous region, or municipal level.

The MAH shall also include information on drug recalls carried out during the reporting period in the annual drug report.

Article 21 If a drug manufactured outside of China is subject to a recall within China, the domestic agent—that is, the legal person enterprise designated by the overseas MAH to fulfill holder obligations in China—shall organize and implement the recall in accordance with this regulation, and report the recall and its handling to the local drug regulatory and health authorities at the provincial, autonomous region, or municipal level.

If a drug recall is initiated outside of China, and upon comprehensive assessment is deemed to fall under any of the following circumstances, the domestic agent shall, within 10 working days of the initiation of the foreign recall, report the drug name, specifications, batch number, recall reason, and other relevant information to the local provincial-level drug regulatory authority:

1-The recalled drug is of the same variety as that marketed in China, but does not involve the same specification, batch number, or dosage form;

2-The recalled drug shares the same production line as a product marketed in China;

3-Other situations where reporting to the drug regulatory authority is required.

The overseas MAH shall comprehensively evaluate the foreign recall. If it is determined that a recall should also be conducted within China, the domestic agent shall organize and implement the recall in accordance with the first paragraph of this Article.

Chapter IV Ordered Recall

Article 22 The provincial, autonomous region, or municipality-level drug regulatory authority shall order the marketing authorization holder (MAH) to recall drugs under any of the following circumstances:

1-The drug regulatory authority, after investigation and evaluation, determines that the MAH should recall the drug but has failed to do so;

2-Upon reviewing the MAH's voluntary recall results, the drug regulatory authority finds the recall to be incomplete.

Article 23 When the provincial, autonomous region, or municipality-level drug regulatory authority issues an order to recall drugs, it shall publish the recall order information to the public in accordance with the relevant provisions of Articles 9 and 15 of this regulation. It shall require the MAH, drug manufacturers, drug distributors, and drug users to cease production, release, sale, and use of the recalled drugs.

The MAH shall carry out the recall as ordered and publish the recall information to the public in accordance with the relevant provisions of Article 15 of this regulation.

Article 24 When the provincial, autonomous region, or municipality-level drug regulatory authority decides to issue a recall order, it shall deliver a written recall order notification to the MAH. The recall order notification shall include the following:

1-Specific information about the recalled drug, including name, specifications, batch number, and other basic details;

2-The reasons for implementing the recall;

3-The results of the review, evaluation, and/or investigation;

4-The recall classification level;

5-The recall requirements, including the scope and timeframe.

Article 25 Upon receiving the recall order notification, the MAH shall, in accordance with the provisions of Articles 14 and 16 of this regulation, notify the drug manufacturers, drug distributors, and drug users; formulate and file a recall plan; and organize the recall implementation.

Article 26 During the recall implementation process, the MAH shall report the progress of the drug recall to the provincial, autonomous region, or municipality-level drug regulatory authority in accordance with the requirements of Article 17 of this regulation.

Article 27 The marketing authorization holder (MAH) shall properly carry out the follow-up handling and record-keeping in accordance with Articles 18 and 19 of this regulation. Within 10 working days after completing the recall and related handling, the MAH shall submit a summary report on the drug recall to the provincial, autonomous region, or

municipality-level drug regulatory authority and the health administration authority at the place of their location.

Article 28 The provincial, autonomous region, or municipality-level drug regulatory authority shall review the summary report within 10 working days of receipt and evaluate the effectiveness of the recall. If necessary, experts may be convened for review and evaluation. If it is determined that the recall has not effectively controlled the risk or eliminated the hazard, the authority shall issue a written request for the MAH to conduct a re-recall.

Article 29 If the MAH violates the provisions of this regulation by refusing to conduct a recall after being ordered by the provincial, autonomous region, or municipality-level drug regulatory authority, or if drug manufacturers, distributors, or users do not cooperate with the recall, the relevant drug regulatory authority shall investigate and handle the matter in accordance with Article 135 of the Drug Administration Law.

Chapter 5: Supplementary Provisions

Article 30 The recall procedures stipulated in this regulation apply to vaccines marketed within China. Requirements for handling vaccines with confirmed or suspected quality issues shall be implemented in accordance with the Vaccine Administration Law.

Article 31 If the domestic MAH discovers quality issues or other safety hazards in exported drugs, they shall promptly notify the drug regulatory authorities and purchasers in the importing country (region). If a recall is necessary overseas, it shall be organized and implemented in accordance with the relevant laws, regulations, and purchase contracts of the importing country (region).

Article 32 The recall of traditional Chinese medicine decoction pieces and traditional Chinese medicine formula granules shall be carried out by their manufacturing enterprises in accordance with this regulation.

Article 33 This regulation shall come into effect on November 1, 2022.